

## REGIONAL MEDICAL PHYSICS DEPARTMENT

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26 May 2000

Docket Management Branch (HFA-305)  
Food and Drug Administration, Room 1061  
5630 Fishers Lane  
Rockville  
Maryland 20857  
USA

Dear Sir

**Docket No. 78N-00388: Sunscreen drug products for over-the-counter human use**

I have read the report and letter submitted by L'Oréal dated 3 March 2000 and am writing to express my concern that the data presented by L'Oréal on the PPD method lack scientific robustness.

The precept that every measurement must be accompanied by an assessment of its uncertainty is fundamental to experimental scientists. When we look carefully at the uncertainties associated with determination of the PPD endpoint, we can only conclude that this *in vivo* marker is unreliable and subject to unacceptably large random and systematic uncertainties. Specifically:

1. The range of PPDs obtained with a given neutral density filter is about a factor of 2; clearly not compatible with the claim on page 10 of the L'Oréal document that "... the PPD response is an accurate dosimeter for UVA radiation".
2. Proper statistical analysis (which L'Oréal failed to do) of the inter-laboratory study given on pages 29 to 32 of the report confirms statistically significant systematic differences between laboratories.

You will realise that these data probably represent the best that can be obtained, submitted, as they were, by protagonists of the method. Adoption of the PPD method as a means of measuring the UVA protection afforded by sunscreens is tantamount to acknowledging that robust scientific methodology has no place in assessing sunscreens for human use. For this reason, if for no other, I urge you not to recommend this technique.

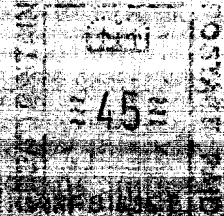
Yours faithfully

Brian L Diffey PhD, DSc  
Professor of Medical Physics  
Professor of Photobiology

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